

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)	
COMPOUNDING PHARMACY, INC.)	MDL No. 2419
PRODUCTS LIABILITY LITIGATION)	Dkt. No. 1:13-md-2419-RWZ
_____)	

This Document Relates to Suits Naming:

Suits Naming Saint Thomas Outpatient
Neurosurgical Center, LLC

**MEMORANDUM IN SUPPORT OF STOPNC DEFENDANTS’
MOTION FOR PARTIAL SUMMARY JUDGMENT
AND
OPPOSITION TO
THE PSC’S MOTION FOR PARTIAL SUMMARY JUDGMENT [Doc. 2300]**

The Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC (“STOPNC”); Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD (frequently referred to as the “Tennessee Clinic Defendants” and herein referred to as the “STOPNC Defendants”) submit this (1) Memorandum in Support of their Motion for Partial Summary Judgment and (2) Opposition to the Plaintiffs’ Steering Committee’s Motion for Partial Summary Judgment [Doc. 2300].

PROCEDURAL SUMMARY

Doc. 2300 marks the Plaintiffs' unprecedented effort to impose unabridged liability without fault on Saint Thomas Outpatient Neurosurgical Center, LLC, a licensed Tennessee health care provider expressly covered by the Tennessee Health Care Liability Act, for contaminated products made and sold by NECC. The STOPNC Defendants oppose the Plaintiffs' Motion for Partial Summary Judgment, and move for partial summary judgment in their favor on the product liability issue. What follows explains both why the Plaintiffs' motion must be denied and why the STOPNC Defendants are entitled to summary judgment on this issue.¹

Contemporaneously, the STOPNC Defendants submit their:

1. Motion for Summary Judgment
2. Response to the Plaintiffs' Statement of Undisputed Material Facts
3. Statement of Undisputed Material Facts in Support of the STOPNC Defendants' Motion²
4. Affidavits of John W. Culclasure, MD and Scott Butler
5. PSC's Responses to Requests for Admissions 1 and 2 and PSC's Supplemental Response to Interrogatory 1
6. Excerpt from deposition of Cindy Williams³
7. Motion to Stay Rulings on these competing motions for partial summary judgment pending resolution of the issue by the Tennessee Supreme Court.

¹ In the interest of efficiency, the STOPNC Defendants file this single brief in opposition to the Plaintiffs' motion and in support of their own motion for partial summary judgment.

² The STOPNC Defendants' Response to the Plaintiffs' Statement of Undisputed Material Facts and Statement of Undisputed Material Facts in Support of their Motion for Summary Judgment are a single pleading.

³ The transcript has been designated confidential by the Saint Thomas Entities. Rather than requiring the STOPNC Defendants to file the entire transcript under seal, the Saint Thomas Entities have agreed to the filing of this excerpt from the transcript.

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INTRODUCTION AND SUMMARY OF ARGUMENT

Reasonable, even-handed application of Tennessee law and persuasive authority, guided by the universal majority rule, matched with the undisputed, material facts of these cases, warrants summary judgment in favor of the STOPNC Defendants on the Plaintiffs' strict product liability claims. By contrast, trusting the Plaintiffs' Memorandum⁴ as an accurate or complete summary of Tennessee law is a mistake. The content of that Memorandum is a pathway to clear error.

First, STOPNC is undisputedly engaged in the business of providing professional health care services to patients in exchange for a fee. No reasonable interpretation of the facts supports the conclusion that STOPNC "engaged in the business of selling" medication injected into the Plaintiffs during their medical procedures. Professional health care *services*, not products, predominate and define the relationship between STOPNC and the patients. STOPNC is not a "seller," an indispensable pre-requisite for application of the Tennessee Product Liability Act ("TPLA") of 1978.

Second, the complaints and undisputed facts establish that the Plaintiffs allege injuries "related to the provision of...health care services," which are governed by Tennessee's Health Care Liability Act ("THCLA") of 2011, "regardless of the theory of liability asserted." The THCLA *does not* allow a finding of strict liability. Liability for an injury "related to the provision of...health care services" *cannot* arise under strict liability in tort.

Despite production of thousands upon thousands of documents, and more than a dozen depositions of witnesses affiliated with STOPNC, the Plaintiffs' product liability claim remains far short of the legal or factual substance necessary to furnish the rule of

⁴ Doc. 2302.

decision in this case. The time has come for the Court to recognize the overwhelming law on this issue, apply it to the undisputed material facts, and grant summary judgment in favor of STOPNC on the product liability claims.

STANDARD OF REVIEW

Summary judgment should be allowed when there is no genuine dispute on any material fact, and the movant demonstrates entitlement to judgment as a matter of law.⁵ The movant bears the initial burden of explaining the basis for its motion and pointing out the absence of any genuine issue of material fact.⁶ “Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial.”⁷ Pointing to a scintilla of evidence in support of the plaintiff’s claim is insufficient to defeat a motion for summary judgment.⁸

* * * * *

“Absent controlling state court precedent, a federal court sitting in diversity may certify a state law issue to the state’s highest court, or undertake its prediction when the course the state courts would take is reasonably clear.”⁹

CERTIFICATION OF ISSUE TO TENNESSEE SUPREME COURT

Viability of the product liability claim is an issue of significance in this litigation. Even the PSC concedes this point.¹⁰ As this Court is aware, despite persistent efforts of members of the PSC to block, and failing that, delay certification, the Middle District of

⁵ FED. R. CIV. P. 56.

⁶ *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

⁷ *Prall v. City of Boston*, 985 F. Supp. 2d 115, 119 (D. Mass. 2013) (internal citations and quotations omitted).

⁸ *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

⁹ *Van Haaren v. State Farm Mut. Auto. Ins. Co.*, 989 F. 2d 1, 3 (1st Cir. 1993) (internal citations and quotations omitted).

¹⁰ Doc. 2350 (The resolution of the product liability issue “will shape the future course of this litigation dramatically.”).

Tennessee – arising in a related declaratory judgment coverage action – has decided to certify the product liability issue to the Tennessee Supreme Court for decision. Rather than attempting to predict what the Tennessee Supreme Court will do, this Court will avoid speculative imprecision by awaiting that decision.¹¹ A contemporaneous motion filed by these Defendants requests that this Court stay the decision until the Supreme Court of Tennessee completes its work.

If this Court elects to establish the law of Tennessee, the process must include not only Tennessee law, but also “guidance in analogous state court decisions, persuasive adjudications by courts of sister states, learned treatises, and public policy considerations identified in state decisional law.”^{12 13}

In the course of that process, this Court will find no support in analogous state court decisions for the Plaintiffs’ contention that STOPNC was “engaged in the business of selling” medications used during medical procedures. Tennessee, like Massachusetts, embraces the “predominant factor” test to determine the law applicable to “hybrid” transactions involving services and ancillary products. Under analogous Tennessee decisions, the undisputed facts here fall squarely on the side of service provider. And, Tennessee decisions interpreting the applicability of the THCLA repeatedly emphasize that the statute encompasses *all* claims related to the provision of such health care services, regardless of the theory of liability asserted.

¹¹ *Seals v. Sears Roebuck and Co.*, 688 F. Supp. 1252, 1256 (E.D. Tenn. 1988) (“Since this question deals directly with legislative policy that is uniquely Tennessee’s, it would be preferable for it to be resolved in the Tennessee courts....[C]ertification of state law questions to state courts provides the most direct and feasible means of clarifying unsettled areas of state law.”).

¹² *Blinzler v. Marriott Intern., Inc.*, 81 F. 3d 1148, 1151 (1st Cir. 1996) (internal citations omitted).

¹³ “As long as these signposts are legible, [the federal court’s] task is to ascertain the rule the state court would most likely follow under the circumstances, even if [the federal court’s] independent judgment on the question might differ.” *Van Haaren*, 989 F. 2d at 3.

The first order conclusion under Tennessee law is clear. STOPNC provided a service to the Plaintiffs; it was not a “seller” of products. The THCLA of 2011 governs.

Likewise, the near-uniform law of sister states warrants dismissal of the Plaintiffs’ claims, as do learned treatises on the subject and any reasonable consideration of public policy.

LAW AND ARGUMENT

I. STOPNC is not engaged in the business of selling the MPA administered to the Plaintiffs during medical procedures.

The TPLA of 1978 permits plaintiffs to bring claims against a seller of a defective product when the manufacturer is insolvent.¹⁴ “Seller” is defined as an individual or entity “engaged in the business of selling a product.”¹⁵

While there is no Tennessee decision precisely on point, the undisputed facts, analogous Tennessee decisions, well-known treatises and tort commentators, and nearly every other state to consider the question, unambiguously lead to the conclusion that STOPNC was not engaged in the business of selling methylprednisolone acetate (“MPA”) administered to patients during epidural steroid injection procedures. No sale means no viable claim for strict liability in tort as a matter of law.

a. The undisputed facts permit a reasonable juror to reach only one conclusion: STOPNC is not “engaged in the business of selling” MPA provided to patients during their procedures.

Consideration of (4) four undisputed material facts of record, with nothing presented by the Plaintiffs to countervail these facts or their import, leads to the unavoidable conclusion that STOPNC is a provider of professional health care services, not a seller of medication to patients.

¹⁴ TENN. CODE ANN. § 29-28-106.

¹⁵ TENN. CODE ANN. § 29-28-102(7).

First, STOPNC, as an ambulatory surgery center (“ASC”), is *definitionally* engaged in the provision of services, not sale of goods.

STOPNC is accredited by the Joint Commission, and licensed as a health care facility under Tennessee Code Title 68, Chapter 11.¹⁶ Tennessee defines an ASC as “any institution, place, or building devoted primarily to the maintenance and operation of a facility **for the performance of surgical procedures....**”¹⁷ Likewise, the federal Centers for Medicare and Medicaid Services (CMS) defines an ASC as “any distinct entity that operates **exclusively for the purpose of providing surgical services** to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.”¹⁸

Under federal and state law, STOPNC is by definition a service provider, not a seller of medication.

Second, although STOPNC *could have* billed the Plaintiffs separately for injected medication (a separate billing code exists), *it did not*.^{19 20 21} Instead, consistent with the predominance of services to its patients, STOPNC charged a single fee (a “global” or

¹⁶ SUMF ¶ 1.

¹⁷ TENN. CODE ANN. § 68-11-201(3) (emphasis added).

¹⁸ 42 CFR § 416.2 (emphasis added).

¹⁹ SUMF ¶¶ 13-14.

²⁰ In fact, CMS prohibited STOPNC from billing separately for the MPA for Medicare beneficiaries, which include many of the Plaintiffs. See 42 CFR § 416.164 (noting that drugs are included as part of the global fee); SUMF ¶ 16. This applied to non-Medicare patients, too. SUMF ¶ 17. STOPNC billed private payors using the same billing codes as Medicare. SUMF ¶ 17.

²¹ At least one Tennessee ALJ has decided that health care providers are still “predominantly engaged in the delivery of health care services” (not sales) in the tax context, even when the health care provider charges patients separately for medication. *In Re: Memphis Kidney & Dialysis Services*, No. P-140905 T-A, at p. 2 (Tenn. State Bd. of Equalization, Admin. Judge for Shelby County, Tenn., Mar. 17, 2003) (“The testimony of Memphis Kidney & Dialysis Services’ administrator establishes that the company is predominantly engaged in the delivery of medical services. Though billed separately for whatever drugs they may receive in connection with those services, Memphis Kidney & Dialysis Services’ clients are essentially paying for dialysis treatment and related services.”). Opinion attached as Exhibit 1.

“facility” fee) of \$1,034²² for all professional services it rendered during the Plaintiffs’ epidural steroid injection procedures.²³

STOPNC’s global fee for the injection procedures covered:

1. A licensed registered nurse to assess the patient’s condition prior to the procedure and after the procedure, and to discharge the patient
2. A certified medical assistant, licensed practical nurse, or certified radiology technician to assist the physician in performing the procedure
3. Use of STOPNC’s facility, including patient rooms and an operating room
4. Use of STOPNC’s equipment, including (1) a fluoroscopy (x-ray) machine to provide the physician with real-time imaging of the patient’s spine and (2) equipment to monitor the patient’s vital signs, both used during the procedure
5. The medications administered during the procedure, including the steroid, contrast dye, saline, and local anesthetic
6. The medical supplies used during the procedure, including latex gloves, gauze, and bandages
7. Administrative services such as recordkeeping, billing, and scheduling.²⁴

* * * * *

Federal law also defines exactly what STOPNC was charging for:

42 CFR § 416.164 Scope of ASC services.

(a) Included facility services. ASC services for which payment is packaged into the ASC payment for a covered surgical procedure under §416.166 include, but are not limited to—

- (1) Nursing, technician, and related services;
- (2) Use of the facility where the surgical procedures are performed;
- ...
- (4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS);
- ...

²² This fee varied slightly depending on the specific type of injection chosen by the physician to best treat the Plaintiff’s pain.

²³ SUMF ¶ 12.

²⁴ SUMF ¶ 12.

- (5) Medical and surgical supplies...;
- (6) Equipment;
- ...
- (11) Radiology services...;
- (12) Administrative, recordkeeping and housekeeping items and services....²⁵

* * * * *

The logical conclusion from the facts, placed in the context of the applicable state and federal law, is that the \$1,034 global facility fee charged by STOPNC was predominantly for services, *not* for a \$6.50 vial of MPA.²⁶ No reasonable juror could find that STOPNC was engaged in the business of “selling” MPA to the Plaintiffs.

* * * * *

Third, STOPNC did not charge the Plaintiffs or their third-party insurance carriers sales tax for the MPA,²⁷ which Tennessee law *requires* for an entity engaged in the business of selling.²⁸

Fourth, STOPNC did not deduct the cost of the MPA (or the cost any of the other medical supplies used during the Plaintiffs’ procedures) as a “cost of goods sold” from its income for federal income tax purposes.²⁹

The conclusion is obvious: STOPNC was not a “seller” of MPA to the Plaintiffs. Incessant repetition of the claim to the contrary does not make it so.

* * * * *

It is also undisputed that Dr. Culclasure administered more than a single vial of MPA to some of the Plaintiffs during their procedures.³⁰ If STOPNC were truly *selling*

²⁵ By the Plaintiffs’ logic, because STOPNC charged a global fee, they “sold” housekeeping products to patients and “sold” the x-ray machine when they used it.

²⁶ SUMF ¶ 12.

²⁷ SUMF ¶ 15; see TENN. COMP. R. & REGS. 1320-5-1-.47 (requiring physicians and surgeons to collect sales tax if they are “engaged in the business of selling” tangible personal property).

²⁸ TENN. CODE ANN. § 67-6-102, -202.

²⁹ SUMF ¶ 18.

the MPA to the Plaintiffs, the cost of the procedure would increase for each additional vial “sold.” Yet, that did not occur. STOPNC’s charge for the procedure *did not change* based on the amount of MPA administered.³¹ The Plaintiffs were not permitted to take partially-used vials of MPA home with them when Dr. Culclasure used less than a whole vial, nor could a patient buy MPA for a steroid injection to be performed elsewhere.³²

The Plaintiffs cannot avoid the undisputed facts that establish STOPNC is an ASC that provided professional health care services to the Plaintiffs for a fee of \$1,034, not a seller of \$6.50-vials of MPA. No reasonable juror applying common sense to these undisputed facts could find commercial “sales” of MPA.

b. The facts cited by the Plaintiffs do not permit a reasonable juror to find that STOPNC was “engaged in the business of selling” MPA.

After more than a year of fervent discovery, the PSC has presented nothing beyond tired conclusory allegations and stretched innuendo upon which a reasonable juror could conclude that STOPNC is “engaged in the business of selling a product,” an essential element of the Plaintiffs’ product liability claim.³³

The PSC cites a handful of facts to support its claim that STOPNC meets the statutory definition of seller. Each fact is addressed below. None of the facts, alone or in combination, makes STOPNC a seller of drugs to the public.

³⁰ SUMF ¶ 20.

³¹ SUMF ¶ 21.

³² SUMF ¶ 22.

³³ See *Prall*, 985 F. Supp. 2d at 119 (noting that Rule 56 mandates summary judgment where party cannot make sufficient showing on essential element of claim after adequate time for discovery).

i. The volume of procedures performed by STOPNC and Dr. Culclasure's compensation structure have nothing to do with whether STOPNC was engaged in the business of selling.

In an effort to make this Court view STOPNC as an illicit enterprise, Plaintiffs state that STOPNC performed 450-500 epidural steroid injection procedures each month. Never do they make any effort to connect this volume of services to characterization of the transaction as a "sale." With the same objective, the PSC states that Dr. Culclasure made more when he worked more.³⁴ In a world-class non sequitur, the PSC contends (without any legal support) that, because of the volume of procedures and pay structure, the Court should treat them as a "distributor."^{35 36}

The TPLA does not define "distributor." *Black's Law Dictionary* defines a distributor as "[a] wholesaler, jobber, or other manufacturer or supplier that sells chiefly to retailers and commercial users."³⁷ *The Oxford Dictionary* defines distributor as "an agent who supplies goods to retailers."³⁸ STOPNC, the end-user of the MPA injected into the epidural space as part of the surgical procedures, was not a distributor, or wholesaler. There is no evidence that STOPNC sold medication to retailers, commercial users, or patients. Nothing in the record establishes STOPNC as a distributor.

Regardless, the PSC must admit that – even accepting the PSC's logical leap of faith – invoking the label "distributor" does not make an entity a "seller."³⁹

³⁴ Doc. 2302 at 9-10. Citations to page numbers in the PSC's brief refer to the page numbers assigned by the PSC at the bottom of the pages of the brief, not those assigned by the CM/ECF system at the top of the pages of the brief.

³⁵ See TENN. CODE ANN. § 29-28-102(7) ("Seller includes a retailer, wholesaler, or distributor...").

³⁶ In fact, interestingly, in the very same section, the PSC concedes that Dr. Culclasure charges only for professional services. Doc. 2302 at 13-14 ("The more epidural steroids that Dr. Culclasure administers, the more money he makes....[T]he Howell Allen Clinic...sends an individual invoice to the patient's private or public insurer for the services of the physician who administered the injection.").

³⁷ *Black's Law Dictionary* (10th ed. 2014).

³⁸ *Oxford English Dictionary* (2nd ed. 1989).

³⁹ *Watts v. Mercedes Benz USA, LLC*, 254 S.W.3d 422, 425-426 (Tenn.App. 2007) *perm.app.den.* (2008).

ii. Ms. Schamberg's single answer in a seven-hour deposition to a vague question is of no consequence to this analysis.

Second, the PSC cites Ms. Schamberg's answer to a single question during her deposition as conclusive "proof" that STOPNC is a "seller" of MPA:

Q. And St. Thomas Neurosurgical provides epidural steroids to patients in exchange for money, correct?

A. That is correct.⁴⁰

This answer – or, more accurately, the formulation of the question – does not make it more or less likely that STOPNC was engaged in the business of selling MPA to the Plaintiffs. Ms. Schamberg's answer accurately reflects that STOPNC "provides" – the act of providing (*i.e.*, a service) – the medication to patients for money. Dr. Culclasure likewise "provides epidural steroids to patients in exchange for money," but the Plaintiffs concede that the fee Dr. Culclasure receives is for professional services.⁴¹

If the PSC truly wanted testimony on this issue, they could simply have asked during any of the five depositions of STOPNC witnesses: *Did STOPNC sell MPA to the Plaintiffs?* The Plaintiffs did not do so in 20+ hours of questioning.

The PSC notably omits the only sworn deposition testimony directly on point on this issue, from Cindy Williams,⁴² the individual who negotiates STOPNC's contracts with health insurance companies:

Q. Do you know whether when a patient receives an epidural steroid injection at St. Thomas Neurosurgical -- first of all, do you know whether St. Thomas Neurosurgical bills the particular payor for that patient?

A. You mean does the center bill for the patient at the facility?

⁴⁰ Schamberg Dep. Tr., 55:11-14.

⁴¹ Doc. 2302 at 13-14 ("The more epidural steroids that Dr. Culclasure administers, the more money he makes....[T]he Howell Allen Clinic...sends an individual invoice to the patient's private or public insurer for the services of the physician who administered the injection.").

⁴² Ms. Williams is employed by one of the Saint Thomas Entities, not STOPNC.

Q. Does the center send a bill for that injection to some payor?

A. The center bills for the services that are considered the technical components of the facility for that -- to that insurance company.⁴³

Even if relevant to the issues, Ms. Schamberg's answer to an intentionally ambiguous question cannot form the basis for summary judgment in favor of the Plaintiffs. In a recent case decided by the 7th Circuit, the court reversed summary judgment entered in favor of Hospira, noting:

...Hospira repeatedly cherry-picked isolated phrases from Malin's deposition and claimed that these "admissions" doomed her case. When the testimony is read in context, however, it becomes clear that Malin made no such admissions, and that Hospira's presentation of the evidence amounted to nothing more than selectively quoting deposition language it likes and ignoring deposition language it does not like.⁴⁴

The Court should not tolerate the PSC's similar strategy here. At its absolute best for the Plaintiffs, this answer is merely a scintilla of evidence, inadequate to meaningfully move the summary judgment scales.

iii. STOPNC's letter to NECC revoking acceptance of MPA has no bearing on this analysis.

Next, the PSC singles out two phrases from a letter from STOPNC to NECC, and claims that these isolated phrases confirm STOPNC's "status as a seller."⁴⁵

In compliance with the Uniform Commercial Code as adopted in Tennessee, STOPNC notified NECC that NECC breached the statutory warranty of merchantability.⁴⁶ The PSC gives no explanation for how this phrase establishes STOPNC (as opposed to NECC) as a seller. The warranty of merchantability requires

⁴³ Williams Dep. Tr. 27:9-20 (emphasis supplied).

⁴⁴ *Malin v. Hospira, Inc.*, 762 F. 3d 553, 564 (7th Cir. 2014).

⁴⁵ Doc. 2302 at 14.

⁴⁶ TENN. CODE ANN. § 47-2-314.

goods be “fit for the ordinary purposes for which such goods are used.”⁴⁷ The rest of the letter, ignored by the PSC, explains that the MPA was not fit for STOPNC to use “in the care of patients.” Timely notification to NECC that it sold a product which was not fit for epidural steroid injections does not make STOPNC a “seller” to patients.

Pursuing the same theme, the PSC highlights STOPNC’s statement to NECC that the MPA was “no longer fit for use/sale” due to contamination. The PSC intentionally conflates NECC’s sale to STOPNC with sale by STOPNC and does not mention the word “use,” even though it is literally next to “sale.” STOPNC put NECC on notice that the MPA was not fit for use by STOPNC or sale by NECC as required by Tenn. Code Ann. § 47-2-607 to preserve STOPNC’s UCC remedies. STOPNC’s decision to assert its rights under the UCC as a purchaser of defective product certainly does not establish it as a seller. The PSC does not even attempt to bridge this logical gap and offers nothing, from Tennessee or elsewhere, to undergird this proposition.⁴⁸

The Plaintiffs’ argument is particularly incomprehensible in light of the fact that *the Plaintiffs* also assert claims against STOPNC *for breach of the same warranty*.⁴⁹ This, of course, does not establish that the Plaintiffs were sellers of the MPA. This inconsistency unmasks the lack of principle and the absence of support for the substantive claims against STOPNC. Nothing in the revocation of acceptance letter from STOPNC to NECC defines the relationship between STOPNC and its patients.

⁴⁷ TENN. CODE ANN. § 47-2-314(2)(c).

⁴⁸ Thinking logically, how does STOPNC (purchaser) asserting a claim against NECC (seller) for providing it a defective product make STOPNC engaged in the business of *selling* that product? The argument is beyond disjointed.

⁴⁹ 2nd Am. Master Compl. ¶ 324.

iv. Amendment to STOPNC's contract with BlueCross BlueShield of Tennessee.

As the final act staged to support its position, the PSC asserts that STOPNC's "contracts with payers establish that the clinic is paid for drugs that it distributes."⁵⁰ This conclusory statement is allegedly supported by an amendment to a contract between STOPNC and BlueCross BlueShield of Tennessee ("BCBST").

The PSC, however, ignores the totality of the underlying contract, repeatedly describing STOPNC as a provider of services:

- BCBST issues "benefits agreements covering the provision of health care services." BCBST Contract ¶ 1 (emphasis supplied).⁵¹
- STOPNC "intends to provide institutional health care services to BCBST members." *Id.* ¶ 1 (emphasis supplied).
- "[T]he parties to this Agreement desire to enter into this Agreement to make available quality health care services to BCBST Members." *Id.* ¶ 1 (emphasis supplied).
- "BCBST Participating Institution' means an institution that has entered into an Institution Agreement with BCBST to provide services to BCBST Members." *Id.* ¶ 2 (emphasis supplied).
- "Institution Services' means inpatient and outpatient services provided by a BCBST Participating institution." *Id.* ¶ 2 (emphasis supplied).
- "Provision of Services. The Institution shall be responsible for providing the medical care and treatment and the maintenance of a patient relationship with each BCBST Member that the institution treats. Institution will provide only those services that it is duly licensed, authorized, and qualified to provide...." *Id.* ¶ 4.1 (emphasis supplied).
- Quality of Care. Institution shall provide health care services to BCBST members in accordance with recognized standards and within the same time frame [*sic*] as those services provided to Institution's other patients...." *Id.* ¶ 4.2 (emphasis supplied).

⁵⁰ Doc 2203 at 14.

⁵¹ The contract is attached as Exhibit 4 to the affidavit of Scott Butler, which is being filed contemporaneously.

The contract also tellingly includes supplies (*i.e.*, drugs) **as part of the services STOPNC provides**: "'Covered Services' means those Medically Necessary health care services and supplies delivered to or provided for BCBST members...."^{52 53}

The PSC's citation to a teaspoon of content, in an amendment to one of STOPNC's third-party payor contracts, while willfully ignoring an ocean of substance describing the work of STOPNC as the delivery of "health care services," misleads and misinforms the Court. The contracts as a whole and the testimony of the individual responsible for negotiating those contracts (Cindy Williams, quoted *supra* pp. 10-11) establish that the contracts cover STOPNC's health care services. They do nothing to establish STOPNC as a seller.

c. Application of the predominant factor test to the undisputed facts establishes, as a matter of law, that STOPNC is not subject to strict liability in tort.

The PSC claims that STOPNC must be treated like the legacy General Motors that sold cars with a defective ignition switch device. Perhaps they will now admit that, at best, they describe a mixed sale/service transaction.⁵⁴

Tennessee, like Massachusetts⁵⁵ and most states, employs the "predominant purpose test" to determine whether a mixed sale/service transaction was predominantly

⁵² BCBST Contract ¶ 2 (emphasis supplied).

⁵³ STOPNC's contracts with other private insurers are equally, if not more, clear that the contracts are for professional health care services. See, *e.g.*, Cigna Contract, at 1 ("Cigna and [STOPNC] desire to enter into this Agreement relating to certain health care services for individuals[.]"); Mission Point Contract, at 1 ("[Mission Point Health Partners] and [STOPNC] mutually desire to enter into an arrangement whereby [STOPNC] will render health care services to Members as part of an accountable care organization, and be reimbursed for such services in accordance with the terms of this Agreement."). Likewise, the Medicare regulations applicable to ambulatory surgery centers, which govern the relationship between STOPNC and its Medicare beneficiary-patients in lieu of a contract, are equally clear that the reimbursement is for services (discussed at length *supra* pp. 5-7).

⁵⁴ The Plaintiffs must admit the epidural steroid injection procedure included provision of medical services by STOPNC. SUMF ¶ 12.

⁵⁵ *Mattoon v. City of Pittsfield*, 775 N.E. 2d 770, 784 (Mass. App. Ct. 2000). Under Massachusetts law, there is no strict liability cause of action for a defective product. *Commonwealth v. Johnson Insulation*,

for a good or a service.⁵⁶ Examining the entire relationship between the parties, the predominant purpose test requires the Court to weigh four (4) factors: (1) the language of the contract; (2) the nature of the business of the supplier of goods and services; (3) the reason the parties entered into the contract; and (4) the amounts paid for the rendition of services and goods, respectively.⁵⁷ The Defendants address each below.

i. The language of the relevant agreements characterize this as an agreement for services.

In examining the language of the contract, courts look to “the terms describing the performance of the parties, and the words used to describe the relationship of the parties.”⁵⁸ “Contractual language that refers to the transaction as a ‘purchase,’ for example, or identifies the parties as the ‘buyer’ and ‘seller,’ indicates that the transaction is for goods rather than services.”⁵⁹

The language in the contract with Blue Cross/Blue Shield of Tennessee repeatedly describes the relationship between STOPNC and the patient as one for the provision of professional services. The contract repeatedly refers to “services” and contains nothing to support the PSC’s claim that the sale of a product predominates.

The consent form executed by the Plaintiffs, additional contemporaneous evidence of the contract between the parties, characterizes the nature of the provider-

682 N.E.2d 1323, 1326 (Mass. 1997). Claims of liability without fault, including alleged breach of the warranty of merchantability or fitness, only arise from transactions of goods, and not the provision of services. *Phillips v. Medtronic, Inc.*, 754 F. Supp. 2d 211, 216 (D. Mass. 2010). The breach of warranty theory is not available in Massachusetts where the predominant factor, thrust, or purpose of the transaction is the rendition of service, with goods incidentally involved. *Mattoon*, 775 N.E.2d at 784.

⁵⁶ *Hudson v. Town & Country True Value*, 666 S.W.2d 51, 54 (Tenn. 1984); *Audio Visual Artistry v. Tanzer*, 403 S.W.3d 789, 796 (Tenn. App. 2012).

⁵⁷ *Audio Visual Artistry*, 403 S.W.3d at 799-804.

⁵⁸ *Id.*

⁵⁹ *Id.*

patient relationship as one for the provision of health care services.⁶⁰ Application of the first element of the four (4) part test establishes predominance of services.

ii. STOPNC's business is as a health care provider, not as a seller of goods.

There can be no dispute that STOPNC is a health care provider, licensed under Tennessee law.⁶¹ Tennessee law treats health care providers as predominantly service providers.⁶² Tennessee and the United States define an ASC as a service provider.⁶³ The undisputed facts establish that STOPNC provides a variety of health care services to patients to treat their pain.⁶⁴ The definitions fit. STOPNC is not a seller of goods.

iii. The reason for entering into the relevant agreements was the delivery of health care services to patients, not a sale of goods.

The Plaintiffs do not allege, nor is there any factual proof to support, that the Plaintiffs sought out STOPNC in order to purchase steroids. The Master Complaint itself eliminates that argument: "The Plaintiffs sought treatment from the Clinic Related Defendants."⁶⁵ Just as the Master Complaint states, the Plaintiffs entered into the

⁶⁰ SUMF ¶ 5 (consent form attached to the affidavit of John Culclasure, MD).

⁶¹ "Health care provider" means...[a] nongovernmental health care facility licensed under title 68, chapter 11." TENN. CODE ANN. § 29-26-101(a)(2). STOPNC is licensed under Tennessee Code, Title 68, Chapter 11. SUMF ¶ 1.

⁶² TENN. CODE ANN. § 29-26-101(b) ("Health care services to persons includes care by health care providers..."); see also, e.g., TENN. CODE ANN. § 7-57-501(b) ("The general assembly hereby finds that the demand for hospital, medical and health care services is rapidly changing, as is the way and manner in which such services are purchased and delivered; that the market for hospital and health care services is becoming increasingly competitive...." (emphasis supplied)).

⁶³ 42 CFR § 416.2; TENN. CODE ANN. § 68-11-201. Even the term "health care provider" – a provider of health care – indicates that STOPNC's business is predominantly service (care), and not a sale of goods.

⁶⁴ The myth that STOPNC is anything other than a provider of professional health care services is completely debunked when the range of services provided by STOPNC is examined. STOPNC provides treatment for patients' pain using a variety of procedures. SUMF ¶¶ 12, 23. Some of those procedures do not rely on medications to provide pain relief. SUMF ¶ 25. Because these procedures do not use a drug, there can be no possible argument that patients are purchasing a drug during those procedures. The nature of STOPNC's business is not magically transformed into that of seller of goods simply based on a physician's professional medical decision to use a procedure that relies on a steroid to provide pain relief versus a procedure that does not. The Plaintiffs' suggestion otherwise is ludicrous.

⁶⁵ 2nd Am. Master Compl., ¶ 151.

relationships with STOPNC to receive medical treatment, not to purchase goods. For example, Plaintiff Mae Parman was referred to STOPNC for treatment of back, hip, and leg pain, believed to have been caused by lumbar stenosis.⁶⁶

Additionally, the BCBST contract, which governs payment for the care rendered, states succinctly: “[T]he parties to this Agreement desire to enter into this Agreement to make available quality health care services to BCBST Members.”⁶⁷

The purpose of the STOPNC-patient transaction was to secure health care services to relieve pain. No patient intended to purchase medication from STOPNC. The Plaintiffs do not even allege this, and they offer no evidence to the contrary.

iv. The relative amounts paid for goods and services further illustrate this was predominantly a service, not a sale.

No doubt should exist as to whether STOPNC provided a service under the predominant factor analysis. The final factor, comparing the cost of the MPA to the cost of the services provided, drives the point home. The cost of the medication is miniscule when compared to the amount charged for the service.

STOPNC charges approximately \$1,034 for epidural steroid injections.⁶⁸ STOPNC paid \$6.50 per vial of MPA from NECC.⁶⁹ MPA (the good) accounted for less than one percent (1%) of the total charge for the procedure. The remainder of the \$1,034 fee was overwhelmingly service-based. Even if the cost of all medical supplies used during the procedure is factored in (less than \$40 in total) and the average

⁶⁶ SUMF ¶ 4.

⁶⁷ BCBST Contract ¶ 1 (emphasis supplied).

⁶⁸ SUMF ¶ 12.

⁶⁹ SUMF ¶ 8.

reimbursement⁷⁰ STOPNC received for the procedure is used (around \$370), the goods used during the procedure still account for less than 11% of the procedure's total cost.⁷¹

Correctly finding that the transaction was predominately one for service, instead of the sale of goods, eliminates liability without fault *even if* the Court concludes that there was an incidental sale of a tangible product.⁷² For example, in *Dove v. Ruff*,⁷³ Dr. Ruff, an allergist, compounded his own medication administered to a child, for which he made a separate, distinct charge of \$24.00. The child received the injection, and experienced a severe anaphylactic reaction, with subsequent brain damage. The court dismissed the claims for strict liability in tort and other theories of liability without proof of fault. The plaintiff's remedy arose, just as the Defendants here insist, under the Indiana Medical Malpractice Act.⁷⁴

II. The Plaintiffs claim injury "related to the provision of...health care services," making their claims subject to Tennessee's Health Care Liability Act, which precludes liability without proof of fault.

Interpreting legislative enactments, Tennessee courts apply the plain meaning without complicating the task.⁷⁵ The Court must enforce the plain and ordinary meaning of the statute.⁷⁶

⁷⁰ STOPNC charged \$1,034 for epidural steroid injections. However, the contracts with the various insurers (or Medicare regulations) determines the amount of money STOPNC actually receives.

⁷¹ SUMF ¶ 27.

⁷² See *Pass v. Shelby Aviation*, 2000 WL 388775 (Tenn. App. 2000) (finding, where the plaintiff claimed that the rear-wing attachment point brackets sold and installed by the defendant were defective, that services predominated); *Mattoon*, 775 N.E.2d at 784 (finding water was "sold" to the plaintiff for a fee, but concluding the predominant factor, thrust, or purpose of the transaction was rendition of service).

⁷³ 558 N.E.2d 836 (Ind. App. 1990).

⁷⁴ *Dove*, 558 N.E.2d at 840. See also *Preston v. Thompson*, 280 S.E.2d 780, 784 (N.C. App. 1981). In *Preston*, the plaintiff sought to hold the defendant dentist liable without fault, under the Uniform Commercial Code, for dentures. The court held: "We adhere to the general and majority rule that those who, for a fee, furnish their professional medical services for the guidance and assistance of others are not liable in the absence of negligence or intentional misconduct."

⁷⁵ *Eastman Chem. Co. v. Johnson*, 151 S.W.3d 503, 507 (Tenn. 2004).

⁷⁶ *Abels v. Genie Indus., Inc.*, 202 S.W.3d 99, 102 (Tenn. 2006).

Here, the undisputed facts demonstrate that the Plaintiffs' claims "relate[] to the provision of...health care services."⁷⁷ As such, the claims are subject to the THCLA, regardless of the label chosen by the author of the complaint, or the theory of liability on which the action is ostensibly based.⁷⁸

The plain language of the THCLA bars liability without fault. The Act explicitly requires a plaintiff to prove that STOPNC departed from the accepted standard of professional practice, causing the Plaintiffs' injuries, before recovery.⁷⁹ Indeed, the Act explicitly prohibits a presumption of negligence in health care liability actions.⁸⁰

a. STOPNC, a health care provider, provided health care services to the Plaintiffs.

The care provided by STOPNC's staff to the Plaintiffs certainly falls within the statutory definition of "health care services."⁸¹ The Plaintiffs concede as much in their complaints.⁸² There is no reasonable dispute that STOPNC, a health care provider, provided health care services to the Plaintiffs.

b. The Plaintiffs allege injuries "related to" these health care services.

The THCLA governs any claim for injury "related to" the provision of health care services.⁸³ That the Plaintiffs allege injury "related to" the health care services provided by STOPNC – placing the suit squarely within the THCLA – is inescapable.⁸⁴

⁷⁷ TENN. CODE ANN. § 29-26-101.

⁷⁸ *Id.* § 29-26-101.

⁷⁹ *Id.* § 29-26-115(a).

⁸⁰ *Id.* § 29-26-115(c) (absent some exceptions not applicable here).

⁸¹ SUMF ¶ 12; *Id.* § 29-26-101 ("care by health care providers, which includes care by physicians, nurses, licensed practical nurses, pharmacists, pharmacy interns or pharmacy technicians under the supervision of a pharmacist, orderlies, certified nursing assistants, advance practice nurses, physician assistants, nursing technicians and other agents, employees and representatives of the provider, and also includes staffing, custodial or basic care, positioning, hydration and similar patient services").

⁸² 2nd Am. Master Compl., ¶ 151.

⁸³ TENN. CODE ANN. § 29-26-101.

⁸⁴ Without the health care services at the heart of the cases, the Plaintiffs would have suffered no injury. How, then, could the Plaintiffs' claims for injury *not* relate to the provision of health care services?

First, the Court need not look beyond the Plaintiffs' own complaints, where the Plaintiffs unambiguously allege injury suffered during health care services.⁸⁵

Even without the plain admissions in the complaints, it is impossible to separate the injection of the medication from the medical treatment. It was an intended element of the medical treatment. STOPNC did not offer a vial of MPA for self-administration by a patient at their leisure; the medication was administered by a licensed physician (with assistance from other STOPNC health care providers) in a licensed health care facility, through a syringe guided into the epidural space utilizing fluoroscopic guidance.⁸⁶

The Plaintiffs cannot avoid the plain language of the statute. The "transaction" (the administration of the medication) is obviously "related to" the provision of health care services. No matter how the Court characterizes the relationship between STOPNC and the Plaintiffs – as health care services, or as an incidental sale of medication during the provision of health care services – the injury complained of due to the injection of the medication "relates to the provision of health care services." This required application of the THCLA.

c. The THCLA applies; and, under the THCLA, STOPNC cannot be held strictly liable because the THCLA precludes liability without proof of negligence.

The plain language of the THCLA dictates that it applies to *all* of the Plaintiffs' claims. The THCLA requires that a plaintiff prove a departure from the standard of acceptable professional practice and that the departure caused the injury.⁸⁷ It explicitly

⁸⁵ 2nd Am. Master Compl. ¶ 153 ("As part of this medical treatment, the Clinic Related Defendants administered NECC contaminated drugs, and/or NECC drugs suspected to be contaminated, to the Plaintiffs.").

⁸⁶ SUMF ¶¶ 1, 2, 3, 6, 7, 12.

⁸⁷ TENN. CODE ANN. § 29-26-115.

prohibits any claim proceeding with a presumption of liability,⁸⁸ contrary to the TPLA's strict liability scheme.⁸⁹ There just is no strict liability under the THCLA.

The Plaintiffs cannot escape the burden of proof requirements of the THCLA by unilaterally electing their claims to proceed under a different statutory scheme. The Court must apply the THCLA and grant summary judgment on the Plaintiffs' TPLA claims because the THCLA – and its burden of proof requirements – governs.

d. Any inconsistency between the THCLA and the TPLA must be resolved in favor of the THCLA.

The THCLA expressly governs “any civil action...alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.”⁹⁰ Intending no understatement of the scope of the THCLA, the legislature made clear the THCLA applied “regardless of any other claims, causes of action, or theories of liability alleged in the complaint.”⁹¹ Applicable substantive law was not to be left to the art of the draftsman of the complaint.

The Products Liability Act of 1978 must yield to any overlap with the Health Care Liability Act of 2011. Where two acts conflict and cannot be reconciled, the prior act is repealed or amended by implication to the extent of the inconsistency between them.⁹²

⁸⁸ TENN. CODE ANN. § 29-26-115(d).

⁸⁹ If there remains any doubt which statute to apply, as the more recent and more specific statute (amended in 2011 and specifically governing claims against health care providers), the THCLA must govern if there is a conflict between the THCLA and the TPLA. *Posadas v. National City Bank*, 296 U.S. 497, 503 (1936) (more recent statute trumps conflicting earlier statute); *Long Island Care at Home, Ltd. v. Coke*, 127 S. Ct. 2339, 2348 (U.S. 2007) (internal citations omitted) (more specific statutory provision trumps a conflicting general statutory provision).

⁹⁰ TENN. CODE ANN. § 29-26-101(a)(1).

⁹¹ *Id.* § 29-26-101(c).

⁹² *Jenkins v. Loudon County*, 736 S.W.2d 603, 607-608 (Tenn. 1987)

III. In predicting how the Tennessee Supreme Court would decide this issue, the Court should look to (1) analogous Tennessee law, (2) tort treatises, and (3) persuasive authority from other states, all of which near-unanimously recognize that health care providers cannot be held strictly liable for defective medical supplies used when treating patients.

Even if this Court were to minimize (1) the undisputed facts cited above applied to the definition of “seller” in the Act, (2) the predominant factor test, and (3) the plain language of the THCLA, and simply seek to decide the general question (do health care providers “sell” medication used incidental to medical procedures?), one conclusion still awaits at the end of the path: The Plaintiffs’ strict liability “sale” claim fails.

In deciding this question of state law, this Court must endeavor to predict how the Tennessee Supreme Court would decide, seeking “guidance in analogous state court decisions, persuasive adjudications by courts of sister states, learned treatises, and public policy considerations identified in state decisional law.”⁹³ The Court cannot ignore these persuasive “signposts.”⁹⁴ These signposts all point overwhelmingly, with virtually no dissonance, to the conclusion that STOPNC, a health care provider, cannot be held strictly liable for a defective medication administered during a medical procedure.

a. Analogous Tennessee law.

Tennessee’s decisional law and the legislative history of the TPLA and THCLA counsel against permitting the Plaintiffs’ strict liability claim to proceed.

⁹³ *Blinzler*, 81 F.3d at 1151 (internal citations and quotations omitted).

⁹⁴ *Id.*

i. Analogous case law indicates Tennessee disfavors applying a strict liability rule in claims for professional health care negligence.

There is a single Tennessee appellate decision – *Burris*⁹⁵ – involving a plaintiff's attempt to sue a health care provider for product liability. The Tennessee Court of Appeals held that the plaintiff's product liability claim against a hospital for a defective product used during a medical procedure was subject to the THCLA's predecessor.⁹⁶ Today's THCLA is broader than the language used to determine scope of the predecessor act in *Burris*. *Burris* is analogous case law that supports the Defendants' position. Plaintiffs offer no contrary Tennessee decision.

ii. In 2015, the Tennessee Supreme Court in *Ellithorpe v. Weismark* provided this Court a clear "signpost" on the scope of the THCLA by recognizing that the THCLA applies broadly to any and all lawsuits that allege injury related to the provision of health care.

Twenty-five years after *Burris* (and a little over a year after this Court's decision on the Defendants' motion to dismiss the Plaintiffs' product liability claim), the Tennessee Supreme Court issued its unanimous opinion in *Ellithorpe v. Weismark*,⁹⁷ illustrating the broad reach of the THCLA despite the efforts of the plaintiff to avoid application of the Act:

Giving every word in this section its full effect and plain meaning, we hold that section 29-26-101 establishes a clear legislative intent that **all** civil actions alleging that a covered health care provider or providers have caused an injury related to the provision of, or failure to provide health care services be subject to the pre-suit notice and certificate of good faith requirements [of the THCLA], regardless of any other claims, causes of action, or theories of liability alleged in the complaint.⁹⁸

⁹⁵ *Burris v. Hosp. Corp. of Am.*, 773 S.W.2d 932 (Tenn. App. 1989). This Court discussed *Burris* in its order on the Defendants' motion to dismiss. Doc. 1360. Thus, the facts will not be repeated here.

⁹⁶ *Id.*

⁹⁷ *Ellithorpe v. Weismark*, --- S.W.3d ---, 2015 WL 5853873 (Tenn. Oct. 8, 2015)

⁹⁸ *Id.* at *7 (emphasis in original).

The Supreme Court did not stop there. It also looked at its previous holding in *Estate of French v. Stratford House*, 333 S.W.3d 546 (Tenn. 2011), which instructed courts to examine each claim individually, on an ad hoc basis, to determine the “gravamen” of the action, and overruled this instruction.⁹⁹

The PSC urges the Court to apply the overruled *Estate of French* analysis and examine each claim individually, applying the TPLA on one hand and the THCLA on the other, to the same set of factual allegations. This directly contradicts the holding in *Ellithorpe*, which requires an analysis of the entire action, and application of the THCLA to every action alleging injury related to the provision of health care services.¹⁰⁰

iii. Legislative history and identified policy considerations demonstrate that the THCLA was intended to stop exactly what the Plaintiffs here try to do.

In addition to *Burris* and *Ellithorpe*, the legislative history of the TPLA and THCLA establish that claims against a health care provider related to a medical procedure should be governed by the THCLA, not the TPLA.

Historically, Tennessee plaintiffs attempted to recast their health care liability claims as other types of claims, to avoid the burden of proof requirements.¹⁰¹ The legislature unabashedly intended to end to this practice by passing the THCLA, as statements from the THCLA's sponsoring senator, Senator Mark Norris, demonstrate:

It is advantageous in the minds of some plaintiffs to keep [their lawsuit] out from under the health care provider statutes, make a cause of action look like

⁹⁹ *Id.*

¹⁰⁰ Although *Estate of French* has been abrogated by the THCLA and *Ellithorpe*, its reasoning on one issue remains instructive. In *Estate of French*, the Tennessee Supreme Court held that negligence *per se* claims could not be asserted in medical malpractice cases. 333 S.W.3d at 561. Declaring conduct negligent *per se* removes the requirement that a plaintiff prove fault. *Id.* The court reasoned that this conflicts with the THCLA's prohibition against presumptions of negligence on the part of the defendant. This again indicates the legislature's intention that, in cases of health care negligence, the plaintiff bear the burden to prove wrongful conduct.

¹⁰¹ See, e.g., *Estate of French*, 333 S.W.3d at 549-50.

something it isn't at its core, so you spend most of your time at the outset trying to define what the cause of action is. We're hopeful that this statute will obviate some of that and reduce some of that time and expense.¹⁰²

Sanctioning the Plaintiffs' strict liability claims in the health care context runs counter to the expressed intent of the THCLA – to ensure that plaintiffs cannot creatively plead around the requirements of the THCLA.

By contrast, the legislative history of the TPLA reflects an intent *not* to apply the TPLA's exception to "manufacturer only" liability in a setting like this. When debating whether to permit strict liability in tort for any party other than the manufacturer under the TPLA, the senators repeatedly referred to Sears and Roebuck as the type and scale of business intended to shoulder liability in the event of insolvency of the manufacturer.¹⁰³ Sears and Roebuck was the quintessential "seller" at the time, like Amazon or WalMart of today. The legislative history makes clear that the legislature had no intention to require a physician's office, or a single surgery center, to bear liability for a defective pharmaceutical made by a now insolvent Johnson & Johnson, Valeant, or Teva Pharmaceuticals.

The legislature intended to limit strict seller liability to the manufacturer, or a retailer with the size and scale of WalMart or Amazon, in order to reduce the costs of product liability insurance.¹⁰⁴ Holding health care providers strictly liable for defective medical supplies would have the opposite effect, making health care providers the *de facto* insurer of thousands of medical supplies they use and requiring virtually every

¹⁰² Discussion begins at 1:04:00 of the recording of the legislative history available at http://tnga.granicus.com/MediaPlayer.php?view_id=196&clip_id=4266.

¹⁰³ See excerpts from legislative history of TPLA at 53-54, 70 attached as Exhibit 2 (handwritten corrections in original transcription).

¹⁰⁴ *Penley v. American Honda*, 31 S.W.3d 181, 186 (Tenn. 2000) ("As the preamble to the TPLA indicates, the General Assembly perceived that uncertainty as to future liability increased the premiums for product liability insurance, which in turn increased the costs of production and ultimately consumer prices.").

health care provider to begin purchasing product liability insurance.¹⁰⁵ The net result would be to further inflate the already ballooning cost of health care.¹⁰⁶

iv. *Owens* does not support the Plaintiffs' position.

Finally, the PSC relies on *Owens v. Truckstops of America*,¹⁰⁷ for the concept that STOPNC can be held both strictly and jointly and severally liable for the contaminated MPA. The PSC's reliance is misplaced.

Owens did not involve a claim for strict seller liability against a service-provider, let alone a health care provider. *Owens* lacks the fit of *Burris* and the timeliness and scope of *Ellithorpe*, and it cannot be reconciled with the plain language of the statutes at issue or their legislative history.

Second, setting aside its inapplicability, the PSC broadly overstates that case's holding with respect to joint and several liability. *Owens* stands for two propositions:

1. Parties in the "chain of distribution" of a defective product are jointly and severally liable for the harm caused by the product.
2. Defendants in a product liability suit may assert comparative fault as a defense.¹⁰⁸

The PSC's attempt to define "chain of distribution" to include all "up-stream parties" has no support in Tennessee law or in fact. The absurdity of the effort to fit *Owens* here is further exposed by the PSC's request that the Court find that the *FDA* and *Massachusetts Board of Pharmacy* are in the "chain of distribution" of the contaminated medication. This absurd application is a good indication to the Court that *Owens* has little, if any, application here.

¹⁰⁵ *Ayyash v. Henry Ford Health Sys.*, 210 Mich. App. 142, 146-47 (1995).

¹⁰⁶ *Id.*

¹⁰⁷ 915 S.W.2d 420 (Tenn. 1996).

¹⁰⁸ *Id.* at 433.

b. Treatises and well-respected tort commentators uniformly state that health care providers are not sellers of medications used incidental to medical procedures.

Like the clear principles of Tennessee law set forth above, well-known treatises and tort commentators agree that health care providers are not sellers of the pharmaceuticals used in medical procedures.

Prosser and Keaton on Torts, the time-tested standard reference, routinely relied upon by the Tennessee Supreme Court,¹⁰⁹ notes:

Hospitals, medical doctors, and other professionals who provide health care services have not generally been held strictly liable even when, in the course of rendering health care services, defective products are transmitted. They are not regarded as the kind of enterprisers, akin to the producer of mass products, that can conveniently bear the costs of accidents attributable to defective things used and transmitted. **Moreover, the principal thing bargained for is not the product transmitted but the professional services of the defendant.**¹¹⁰

Tennessee courts often look to the American Law Report for guidance.¹¹¹ A.L.R. has gathered cases from across the country and, like Prosser, recognized that the majority rule prohibits the imposition of strict product liability against a health care provider for injury caused by a defective medication or device used during medical treatment.¹¹²

¹⁰⁹ See *Shore v. Maple Lane Farms, LLC*, 411 S.W.3d 405, 415-17 (Tenn. 2013) (following *Prosser* for guidance on tort of nuisance); *Hodge v. Craig*, 382 S.W.3d 325, 342 (Tenn. 2012) (deceit and misrepresentation); *Hughes v. Metro. Gov't of Nashville & Davidson County*, 340 S.W.3d 352, 370 (Tenn. 2011) (assault and battery); *Starr v. Hill*, 353 S.W.3d 478, 482 (Tenn. 2011) (family purpose doctrine).

¹¹⁰ W. Prosser and W. Page Keeton, *Prosser and Keeton on Torts*, § 104, at 720 (5th ed.1984) (emphasis supplied).

¹¹¹ See *State v. Rollins*, 188 S.W.3d 553, 568-69 (Tenn. 2006) (noting A.L.R.'s identification of majority rule); *Coyle v. Erickson*, No. E2010-02585-COA-R9-CV, 2011 WL 3689157, *7 (Tenn. App. 2011) (same); *Berry v. Houchens Market of Tennessee, Inc.*, 253 S.W.3d 141, n. 1 (Tenn. App. 2007).

¹¹² Liability of Hospital or Medical Practitioner under Doctrine of Strict Liability in Tort, or Breach of Warranty, for Harm Caused by Drugs, Medical Instrument, or Similar Device used in Treating Patient, 65 A.L.R. 5th 357 (1999).

Perhaps most importantly, in deciding novel questions of law, Tennessee courts look repeatedly to the RESTATEMENT OF TORTS.¹¹³ Indeed, the Tennessee Supreme Court has already adopted part of the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY (1997).¹¹⁴ It follows that, if faced with this question, the Tennessee Supreme Court would likely follow the RESTATEMENT, particularly when the Plaintiffs can cite nothing from respected, national commentators to support their position.

The RESTATEMENT (THIRD) OF TORTS recognizes that health care providers are *not* subject to strict product liability: “It should be noted that, in a strong majority of jurisdictions, hospitals are held not to be sellers of products they supply in connection with the provision of medical care, regardless of the circumstances.”¹¹⁵

¹¹³ Tennessee cases that adopt or take guidance from the RESTATEMENT are too numerous to cite. A search of the Tennessee appellate case law database for “Restatement” returns over 1,500 cases. When faced with an open question in Tennessee law, Tennessee courts often adopt the approach set forth by the RESTATEMENT. See, e.g., *Jones v. State*, No. M2012-02546-SC-S09-CV, 2013 WL 6795237, *6 (Tenn. Dec. 23, 2013) (adopting RESTATEMENT (SECOND) OF TORTS position on immunity from defamation claims); *Cullum v. McCool*, No. E2012-00991-SC-R11-CV, 2013 WL 6665074, *5 (Tenn. Dec. 18, 2013) (citing to former case that adopted RESTATEMENT (SECOND) OF TORTS description of duty of business owners in premises cases).

¹¹⁴ *Davis v. Komatsu American Indus. Corp.*, 42 S.W.3d 34, 43 (Tenn. 2001) (adopting § 5(b) and § 5, cmt. e).

¹¹⁵ REST. (THIRD) OF TORTS: PRODUCT LIABILITY, § 20, cmt. d; see also Reporters’ Notes to § 20, cmt. d (“Hybrid cases often arise in the medical context, as when a surgeon uses defective forceps during an operation. Most jurisdictions hold that hospitals and doctors provide a service – medical treatment – and immunize them from strict liability for harm from defective products used in medical treatment....” (internal citations omitted)); Reporters’ Notes to § 19, cmt. f (“Courts are unanimous in refusing to categorize commercially-provided services as products for the purposes of strict liability in tort. Thus, strict products liability does not extend to professionally-provided services, such as medical or legal help.” (internal citations omitted)).

c. The majority rule is that health care providers are not subject to strict liability as “sellers” of medications used incidental to medical procedures.

Finally, virtually every state that has considered this issue holds that health care providers are not subject to strict liability for a defective product used during treatment of a patient.¹¹⁶ The following jurisdictions have decided the issue:

<u>No Strict Liability</u>		<u>Strict Liability</u>
1. California	15. Mississippi	1. Alabama
2. Colorado	16. New Hampshire	2. Ohio
3. Connecticut	17. New Jersey	
4. District of Columbia	18. New Mexico	
5. Florida	19. New York	
6. Georgia	20. North Carolina	
7. Illinois	21. Oklahoma ¹¹⁷	
8. Indiana	22. Pennsylvania	
9. Kansas	23. South Carolina	
10. Louisiana	24. Texas	
11. Maryland	25. Washington	
12. Michigan	26. West Virginia	
13. Minnesota	27. Wisconsin	
14. Missouri		

The Plaintiffs offer no basis for this Court to predict that the Tennessee Supreme Court would depart from the majority rule.¹¹⁸

* * * * *

The First Circuit directs this Court to look to (1) analogous Tennessee law, (2) treatises and tort commentators, and (3) persuasive decisions from other states, to predict whether the Tennessee Supreme Court would hold STOPNC, a health care provider, strictly liable for contaminated medication administered incidental to health care. These signposts are beyond “reasonably clear” here.¹¹⁹ Any reasonable predictor

¹¹⁶ With their motion to dismiss, the Defendants filed a summary of the case law from other jurisdictions. Attached as Exhibit 3 is an updated summary, adding a case from Louisiana to the previous summary.

¹¹⁷ Federal courts interpreting Oklahoma law.

¹¹⁸ *E.g.*, *Allen v. McPhee*, 240 S.W.3d 803, 823 (Tenn. 2007) (“We adopt the majority rule....”); *McCann v. Hatchett*, 19 S.W.3d 218, 222 (Tenn. 2000) (“...we now adopt the majority rule...”); *Dickinson v. Bain*, 921 S.W.2d 189, 193 (Tenn. 1996) (“This court adopts the majority rule....”); *McIntyre v. Balentine*, 833 S.W.2d 52, 56 (Tenn. 1992) (adopting doctrine of comparative fault and acknowledging that comparative fault is also the law in 45 other states).

¹¹⁹ *Van Haaren*, 989 F. 2d at 3.

of the Tennessee Supreme Court's finding on this issue – with these undisputed facts – would come down on the side of the Defendants.¹²⁰

CONCLUSION

The Plaintiffs repeat the superficially appealing, but legally empty, argument that health care providers should “stand behind their product.” The problem for the PSC is that this was not STOPNC's product. NECC manufactured the defective product, misrepresented its sterility, sent it to an unknowing user, and then wrapped itself, and all of its affiliates, in the sanctuary of the Bankruptcy Court. The Defendant health care providers did not manufacture – or sell – the product. Citing expediency for victims of NECC, Plaintiffs ask the Court to victimize health care providers – from rural nurse practitioners to hospitals – by making them subject to strict liability in tort claims for every product (gauze pads to equipment to medications) used as they deliver services to patients. As the Defendants' brief demonstrates, this effort has been rejected over and over again, for principled reasons, by Courts throughout the United States.

Time has run out on the Plaintiffs' theory of strict liability. Summary judgment for the Defendants on this claim is long past due. STOPNC respectfully requests an order (1) GRANTING its motion for partial summary judgment on the Plaintiffs' strict liability claims and (2) DENYING the Plaintiffs' motion for partial summary judgment.

¹²⁰ The Plaintiffs have obviously seen the writing on the wall, as evidenced by their repeated efforts to actively prevent, or failing that, delay a Tennessee court from deciding this question. The Defendants initially sought a determination on this issue in cases filed in state court in Tennessee in early 2013. While the motion was pending, the plaintiffs voluntarily dismissed those cases and refiled them in federal court for transfer to the MDL. Recently, the PSC vehemently opposed certification of the issue to the Tennessee Supreme Court in a declaratory judgment action against another Tennessee clinic involved in these cases by moving for review of the Magistrate's order that the question would be certified and subsequently asking the JPML to transfer the declaratory judgment action to the MDL (both attempts failed).

Respectfully submitted,

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** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 3rd day of December, 2015.

/s/ Chris J. Tardio

Chris. J. Tardio